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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/809,638 | 03/24/2004 | Jun Feng | DPP-IV-5004-C3 | 8935 |
| 32793 | 7590 | 10/25/2006 | | |
| TAKEDA SAN DIEGO, INC. 10410 SCIENCE CENTER DRIVE SAN DIEGO, CA 92121 | | | EXAMINER HABTE, KAHSAI | |
| | | | ART UNIT 1624 | PAPER NUMBER |

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/809,638

Applicant(s)

FENG ET AL.

Examiner

Kahsay Habte

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-49 are pending in this application.

Election/Restriction

2. Applicant's election with traverse of Group XIII (wherein J = K = L = M = CR₁₂ and Q = CO, CS or C=NR₉) filed on 10/4/2006 is acknowledged. Applicants elected a quinazoline species disclosed in Example 6. Since applicants amended the claims to limit the invention to Group XIII, the examiner has searched all the claims.

Information Disclosure Statement

3. Applicant's Information Disclosure Statement, filed on 9/26/2006, 9/7/2006, 8/16/2006, 04/10/2006, 9/14/2005, 8/2/2005 and 2/23/2005 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 11-12 and 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Barnickel et al. WO 01/23364 A1. Cited reference at page 1 discloses quinazoline derivatives that are the same as applicants. Specifically, cited reference at

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pages 49-50 teaches 4 compounds: 3-(3-aminomethyl-cyclohexylmethyl)-2-[2-(4-dimethylamino-phenyl)-vinyl]-6-chloro-3H-quinazoline-4-one; 3-(3-aminomethyl-cyclohexylmethyl)-2-[2-(4-dimethylamino-phenyl)-vinyl]-6-methyl-3H-quinazoline-4-one; 3-(3-aminomethyl-cyclohexylmethyl)-2-[2-(4-dimethylamino-phenyl)-vinyl]-7-chloro-3H-quinazoline-4-one; and 3-(3-aminomethyl-cyclohexylmethyl)-2-[2-(4-dimethylamino-phenyl)-vinyl]-6-methoxy-3H-quinazoline-4-one that are the same as applicants when applicant's Formula XIX have the following substituents:

Q = CO; R₁ = substituted cyclohexylmethyl (i.e. Z = CH₂ and R_m = cyclohexyl substituted by aminomethyl); R₃ and R₄ = methyl-, chloro- or methoxy-substituted benzo; and R₂ = -CH=CH-4-dimethylaminophenyl (the N atom is separated by 6-atoms from the vinyl linker). The examiner has attached STN printout that shows these 4 compounds.

5. Claims 21-25, 28-33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Somasekhara et al. Indian Journal of Pharmacy (1972), 34(5), 121-2. Cited reference at page 122 discloses two compounds of interest: 6-chloro-2-cyclopropyl-3-(phenylmethyl)-4(3H)-quinazolinone; and 6-chloro-2-cyclopropyl-3-(phenylethyl)-4(3H)-quinazolinone that are the same as applicant when applicant's Formula XXXVIII has the following substituents:

Q = CO; R₁ = benzyl or phenylethyl (i.e. Z = CH₂ or CH₂CH₂ and R_m = phenyl); R₁₂ = chloro; and R₂ = cyclopropyl.

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6. Claims 38-45, 47-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Chenard et al. *J. Med. Chem.* **2001**, 44, 1710-1717. Cited reference at page 1711 discloses many quinazolinone compounds e.g. see compounds 6, 7, 10-16 that are the same as applicants when applicants' Formula XXXIX has the following substituents:

R_1 = phenyl substituted with chloro; $U = CH_2$; $R_2 = CH_2-NH-CH_2$ -substituted phenyl; and $R_{12} = fluoro$.

7. Claims 38-41 and 43-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Pattanaik et al. *Indian Journal of Chemistry, Section B; Organic Chemistry including Medicinal Chemistry* (1998), 37B (12), 1304-1306. Cited reference discloses many quinazolinone compounds that are the same as applicants when applicant's Formula XXXIX has the following substituents:

R_1 = phenyl or phenyl substituted with chloro, methyl, methoxy; $U = CH_2$; $R_2 = NH$ -substituted thiazolyl; and $R_{12} = dibromo$.

The examiner has attached STN CAS online search printout that shows the prior art compounds.

8. Claims 38-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Chenard et al. EP 0900568 A2. Cited reference discloses many quinazolinone compounds at pages 2-3 that are the same as applicants when applicant's Formula XXXIX has the following substituents:

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R₁ = phenyl or phenyl substituted with chloro, CF₃ or pyridyl substituted with chloro, methyl; U = CH₂; R₂ = NH-substituted pyridyl or NH-substituted phenyl; and R₁₂ = fluoro or chloro.

The examiner has attached STN CAS online search printout that shows the prior art compounds.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 1-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5, 8-9, 11-17, 19, 23, 26-27, 29, 37-39, 51-57, 83-84, 95, 99 and 111 of copending Application No. 10/809,635. Although the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims and claims 1-5, 8-9, 11-17, 19, 23, 26-27, 29, 37-39, 51-57, 83-84, 95, 99 and 111 of copending Application No. 10/809,635.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 1-49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-33, 36, 42-43, 55-61, 87-88, 95, 99-100 and 103 of copending Application No. 10/809,636. Although

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the conflicting claims are not identical, they are not patentably distinct from each other because there is significant overlap between the instant claims and claims 1-33, 36, 42-43, 55-61, 87-88, 95, 99-100 and 103 of copending Application No. 10/809,636.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. Claim 1 and claims dependent thereon are rejected because the term “substituted” is indefinite. In the absence of the specific moieties intended to effectuate modification by the “substitution” or attachment to the chemical core claimed, the term “substituted” renders the claims in which it appears indefinite in all occurrences wherein applicants fails to articulate by chemical name, structural formula or sufficiently distinct functional language, the particular moieties applicants regards as those which will facilitate substitution, requisite to identifying the composition of matter claimed.

b. In claim 1 or elsewhere in the claims, the phrase "U is a moiety" is indefinite. What is covered by U and what is not? It is recommended that applicants recite specific moieties.

c. In claim 2 or elsewhere in the claims, the term "comprising" is an open-ended language. It is recommended that applicants delete said term from the claims.

d. In claim 1 or elsewhere in the claim, the phrase "V comprises a basic nitrogen atom that is capable of interacting with a carboxylic acid side chain of an active site residue of a protein" is not clear. Is the ring nitrogen capable of interacting with carboxylic acid or the substituent on the ring is capable of interacting with carboxylic acid? The term "comprises" is also an open-ended language.

e. In claim 1 or elsewhere in the claims, the term "thio" is a generic one, indicating the presence of sulfur in some form. As a substituent, it has no one single generally accepted meaning. There could be intended thioxo (=S) or mercapto (-SH). It can also denote replacement by S of some other atom (normally, oxygen or carbon) as in "thioalkoxy", where O is replaced by S. Perhaps some term which began with "thio", like thiophene was intended. Whatever choice is selected must be supported by the specification.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte whose telephone number is (571)-272-0667. The examiner can normally be reached on M-F (9.00- 5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kahsay Habte
Primary Examiner
Art Unit 1624

October 19, 2006